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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,674	02/28/2002	Johannes Bartholomaeus	029310.50986US	2545
23911 7590 12/12/2008 CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300				
EXAMINER				
JONES, DAMERON LEVEST				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
12/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/084,674

Applicant(s)

BARTHOLOMAEUS ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9, 11, 12, 15, 17-19, 21 and 30-32 is/are rejected.
- 7) ☒ Claim(s) 10, 13, 14, 16, 20, 22-29 and 33-67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment to the specification filed 8/25/08.

Note: Claims 1 and 3-67 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Examiner acknowledges Applicant's request for reconsideration filed 8/11/08. Applicant's request has been considered and deemed persuasive-in part for the reasons set forth below.

Double Patenting Rejections

I. The double patenting rejections over US Patent No. 6,558,701 and Serial Nos. 10/665,552; 10/016,130; and 10/084,676 are WITHDRAWN for reasons of record in Applicant's response filed 8/11/08.

II. The provisional rejection of claims 1, 3-9, 11, 12, 15, 17-19, 21, and 30-32 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending application number 10/837,755 is MAINTAINED for reasons of record in the office action mailed 4/24/08 and those set forth below.

Applicant asserts that the rejection should be withdrawn because the application does not disclose at least two different salt forms of tramadol.

Applicant's argument is not persuasive because both sets of claims are directed to formulations that may comprise tramadol. The claims differ in that those of the instant invention are not limited to tramadol. In particular, claim 7 of 10/837,755

disclose that the tramadol is released at two or more different rates. Hence, the skilled artisan would recognize that if two salt forms of the same active ingredient is present then the release rate of the active ingredient can vary. Thus, the applications contain overlapping subject matter.

112 First Paragraph Rejections

The rejection of claim 5 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is MAINTAINED for reasons of record in the office action mailed 4/24/08 and those set forth below.

In summary, Applicant asserts that the rejection should be withdrawn because the claim is commensurate in scope the invention achieved by Applicants.

This is found non-persuasive because Applicant is not entitled to subject matter that was not set forth at the time the invention was filed. Each day new composition are being generated which are encompassed by the terminology of Applicant's claim 5. However, since the specification does not clearly describe the terms of claim 5 so that one may ascertain exactly what species are being claimed for which Applicant had possession of at the time of filing, the written description rejection is deemed proper.

112 Second Paragraph Rejection

The rejection of claim 5 is rejection under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is MAINTAINED for reasons of record in the office action mailed 4/24/08 and those set forth below.

In summary, Applicant asserts that the rejection should be withdrawn because the test for indefiniteness is not whether or not the claims are broad.

Applicant's arguments submitted 8/11/08 are non-persuasive because the claims are not only broad, but indefinite as well. For example, it is unclear what species or how one ascertains what compounds Applicant is defining as slimming drugs, regulatory drugs, etc. Thus, the claims are indefinite and the rejection is deemed proper.

Note: Applicant is respectfully requested to delete the duplicate of 'muscle relaxants' appearing in line 27.

103 Rejection

The 103 rejection is WITHDRAWN for reasons of record in Applicant's response filed 8/11/08.

CLAIM OBJECTIONS

3. Claims 10, 13, 14, 16, 20, 22-29, and 33-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

COMMENTS/NOTES

4. The search of the claims has been expanded beyond Applicant's elected species because no prior art was found which could be used to reject the claims. However, Applicant MUST address and overcome the double patenting and 112 rejections above. In particular, the claims are distinguished over the prior art because the prior art neither anticipates nor renders obvious a formulation having at least two different salts in a solid aggregation of the same active ingredient as set forth in independent claim 1.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

December 8, 2008